



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 16, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-91

David E. Pennington, Owner
Pennington Greens
2500 Ashley Lane
Nampa, Idaho 83651

WARNING LETTER

Dear Mr. Pennington:

We inspected your firm located at 2500 Ashley Lane, Nampa, Idaho, on July 3 and 5, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection on July 5, 2000. The deviations cause your sprouts to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act through links in FDA's homepage at www.fda.gov.

Your firm's sprouts are adulterated within the meaning of 402(a)(4) of the Act because they are prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm. In addition, a dog was observed in your sprout production area.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections.

David E. Pennington, Owner
Pennington Greens, Nampa, Idaho
Re: Warning Letter SEA 00-91
Page 2

If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

For your information, our investigator also noted that you are adding a spa water treatment product, [REDACTED] to wash water used to wash sprouts prior to packaging. You should be aware that under the Act, any ingredient intentionally added to a conventional food like sprouts must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or approved as a food additive causes a food to be adulterated under section 402(a)(2)(C) of the Act. We are unclear as to the actual ingredients in the spa treatment and cannot be assured that they are approved additives or are GRAS. The product labeling does not appear to indicate that the product is intended for food use. It is your responsibility to assure that any ingredients added to your sprouts are approved additives or are GRAS.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa Althar, Compliance Officer at (425) 483-4940 or via e-mail at lalthar@ora.fda.gov.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483 –July 3 and 5, 2000
21 CFR PART 110
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ISDH with disclosure statement